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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TEDDY KOSOGLOU, RUDYARD J. RESS, JOHN T. STRONY, ENRICO P. VELTRI, and WILLIAM HAUER

Appeal 2009-002655[1]
Application 10/057,339
Technology Center 1600

Decided:[2] June 24, 2009

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and MELANIE L. MCCOLLUM, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

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[1] Schering Corporation is the real party in interest.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition that contains at least one sterol inhibitor and at least one cardiovascular agent. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

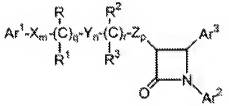
We affirm.

STATEMENT OF THE CASE

Claims 1, 3, 22, 23, 33, 34, 43-46, and 49 stand finally rejected and are on appeal (App. Br. 1). Claim 1 is representative and reads as follows:

1. A composition comprising:

(a) at least one sterol absorption inhibitor represented by Formula (I):



(I)

or isomers thereof, or pharmaceutically acceptable salts or solvates of the compounds of Formula (I) or of the isomers thereof, wherein:

Ar^1 and Ar^2 are independently selected from the group consisting of aryl and R^4-substituted aryl;

Ar^3 is aryl or R^5-substituted aryl;

X, Y and Z are independently selected from the group consisting of $-CH_2-$, -CH(lower alkyl)- and -C(dilower alkyl)-;

R and R^2 are independently selected from the group consisting of $-OR^6$, $-O(CO)R^6$, $-O(CO)OR^9$ and $-O(CO)NR^6R^7$;

R^1 and R^3 are independently selected from the group consisting of hydrogen, lower alkyl and aryl;

q is 0 or 1;

r is 0 or 1;

m, n and p are independently selected from 0, 1, 2, 3 or 4; provided that at least one of q and r is 1, and the sum of m, n, p, q and r is 1, 2, 3, 4, 5 or 6; and provided that when p is 0 and r is 1, the sum of m, q and n is 1, 2, 3, 4 or 5;

R^4 is 1-5 substituents independently selected from the group consisting of lower alkyl, $-OR^6$, $-O(CO)R^6$, $-(CO)OR^9$, $-O(CH_2)_{1-5}OR^6$, $-O(CO)NR^6R^7$, $-NR^6R^7$, $-NR^6(CO)R^7$, $-NR^6(CO)OR^9$, $-NR^6(CO)NR^7R^8$, $-NR^6SO_2R^9$, $-COOR^6$, $-CONR^6R^7$, $-COR^6$, $-SO_2NR^6R^7$, $S(O)_{0-2}R^9$, $-O(CH_2)_{1-10}$-$COOR^6$, $-O(CH_2)_{1-10}CONR^6R^7$, -(lower alkylene)$COOR^6$, $-CH{=}CH$-$COOR^6$, $-CF_3$, $-CN$, $-NO_2$ and halogen;

R^5 is 1-5 substituents independently selected from the group consisting of $-OR^6$, $-O(CO)R^6$, $-O(CO)OR^9$, $-O(CH_2)_{1-5}OR^6$, $-O(CO)NR^6R^7$, $-NR^6R^7$, $-NR^6(CO)R^7$, $-NR^6(CO)OR^9$, $-NR^6(CO)NR^7R^8$, $-NR^6SO_2R^9$, $-COOR^6$, $-CONR^6R^7$, $-COR^6$, $-SO_2NR^6R^7$, $S(O)_{0-2}R^9$, $-O(CH_2)_{1-10}$-$COOR^6$, $-O(CH_2)_{1-10}CONR^6R^7$, -(lower alkylene)$COOR^6$ and $-CH{=}CH$-$COOR^6$;

R^6, R^7 and R^8 are independently selected from the group consisting of hydrogen, lower alkyl, aryl and aryl-substituted lower alkyl; and

R^9 is lower alkyl, aryl or aryl-substituted lower alkyl; and

(b) at least one cardiovascular agent for treating vascular conditions selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof.

The Examiner cites the following documents as evidence of unpatentability:

Rosenblum	US 5,846,966	Dec. 8, 1998

Aram V. Chobanian et al., *Antiatherogenic Effect of Captopril in the Watanabe Heritable Hyperlipidemic Rabbit*, 15 HYPERTENSION 327-331 (March 1990).

Grit Schaarmann et al., *Influence of Soluble Dietary Fibre on the Faecal Excretion of Tocopherol and Blood Lipids in Women*, 19 NUTRITION RESEARCH 689-695 (1999)

A. L. Myasnikov, *The Effect of Some Vitamins on Cholesterol Level and the Development of Experimental Atherosclerosis*, 28 KLIN. MED. U.S.S.R. 3-10 (1950) (abstract only).

Istvan Lelek et al., *The Effect of Essential Fatty Acids on the Plasma Lipoprotein Fractions in Experimentally Induced Atherosclerosis*, 49 ORVOSI HETILAP 1735-1738 (1960) (abstract only).

The following rejections are before us for review:

Claims 1, 3, 22, 23, 33, 34, and 49 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenblum and Chobanian (Ans. 3-5).[3]

Claims 43-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenblum, Chobanian, Lelek, Myasnikov, and Schaarmann (Ans. 5-7).

OBVIOUSNESS -- ROSENBLUM AND CHOBANIAN

ISSUE

The Examiner cites Rosenblum as disclosing the "claimed compounds of Formula (I), such as ezetimibe compound as old and well known in combination with another therapeutic cardiovascular agent such as [a] cholesterol biosynthesis inhibitor" (Ans. 4). According to the Examiner, the compounds of Appellants' formula (I) are "taught as useful for reducing cholesterol and for treating vascular condition such as arteriosclerosis" (*id.*). The Examiner notes that "Rosenblum further teaches that the risk factors

[3] Examiner's Answer mailed March 1, 2006.

associated for atherosclerotic coronary heart disease, include hypertension, serum cholesterol etc." (*id.*).

The Examiner cites Chobanian as teaching "the claimed cardiovascular agent, captopril as old and well known in combination with various pharmaceutical carriers and excipients, in a dosage form (see abstract). This medicament is taught as useful for treating hypertension, and arteriosclerosis, at those levels herein envisioned" (*id.*).

The Examiner notes that

> It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

(*Id.* at 5.) Thus, the Examiner concludes, "[a]s shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-arteriosclerosis agents. It would follow that the recited claims define prima facie obvious subject matter" (*id.*).

Appellants contend that the Examiner failed to make a prima facie case of obviousness because "the desirability of combining the two agents claimed . . . is nowhere shown in the prior art" (App. Br. 9). Appellants urge that "[t]he mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification" (*id.*).

Appellants argue that, rather than combining compounds of Appellants' formula (I) with the claimed antihypertensive agents, Rosenblum only discloses combining its compounds with "a cholesterol

biosynthesis inhibitor, specifically a HMG CoA reductase inhibitor" (*id.* at 10). With respect to Chobanian, Appellants argue that the data supporting captopril's use in treating atherosclerosis is equivocal, and that therefore "the use of captopril alone for treating atherosclerosis in humans is not even strongly suggested in the Chobanian et al. study; further study of the drug is recommended" (*id.*).

Moreover, Appellants urge, even if an ordinary artisan accepted Chobanian's disclosure as suggesting use of captopril for treatment of atherosclerosis, "which Applicants do not concede, it can also be said to teach away from the concept of use of two separate compounds (a compound of formula (I) and a separate cardiovascular agent as claimed) because captopril would serve both functions as an antihypertensive and a treatment for atherosclerosis" (*id.*).

Appellants further contend that "it is never obvious to combine two drugs into one dosage form" (*id.*). Rather, Appellants argue, "[s]afety and efficacy studies of the combined compounds must always be undertaken. There is no way of knowing, prior to such testing, that the compounds, when administered in combination, will have the same profile as the compounds administered separately" (*id.*).

Thus, Appellants contend, combining Rosenblum and Chobanian as posited by the Examiner "renders the present claims at best 'obvious to try', which is not the standard for patentability" and applies improper hindsight reasoning (*id.* at 11). Appellants conclude that an ordinary artisan would therefore "not be motivated by the teachings of Rosenblum et al. and Chobanian et al., . . . to provide a compound of formula (I) and a separate cardiovascular agent as presently claimed" (*id.*).

Appellants do not argue any of the claims subject to this ground of rejection separately. We select claim 1 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner erred in concluding claim 1 would have been obvious to an ordinary artisan where Rosenblum advised the artisan that compounds encompassed by formula (I) of claim 1 were useful for reducing cholesterol and for treating vascular conditions such as arteriosclerosis, where Rosenblum also advised that those compounds were suitably combined with other agents useful in treating vascular disorders, where Rosenblum further advised that risk factors for atherosclerotic coronary heart disease include hypertension and serum cholesterol, and where Chobanian advised the artisan that the ACE inhibitor captopril was useful for treating hypertension, and potentially useful for treating arteriosclerosis.

FINDINGS OF FACT ("FF")

1. Claim 1 recites a composition that has two ingredients, (a) a compound of formula (I), and (b) at least one cardiovascular agent for treating vascular conditions. Claim 1 states that the cardiovascular agent can be an angiotensin-converting enzyme (ACE) inhibitor or an antihypertensive agent.

2. Rosenblum discloses that "[a]therosclerotic coronary heart disease (CHD) represents the major cause for death and cardiovascular morbidity in the western world. Risk factors for atherosclerotic coronary heart disease include hypertension, diabetes mellitus, family history, male gender, cigarette smoke and serum cholesterol" (Rosenblum, col. 1, ll. 26-30).

3. Rosenblum discloses "a method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a compound of formula I. That is, the use of a compound of the present invention as an hypocholesterolemic agent is also claimed" (Rosenblum, col. 3, ll. 44-49).

4. Appellants do not dispute that the compounds of Rosenblum's formula I are encompassed by formula (I) recited in appealed claim 1.

5. Rosenblum also discloses "a method of reducing plasma cholesterol levels, and to a method of treating or preventing atherosclerosis, comprising administering to a mammal in need of such treatment an effective amount of a combination of a hydroxy-substituted azetidinone cholesterol absorption inhibitor of formula I and a cholesterol biosynthesis inhibitor" (Rosenblum, col. 3, ll. 54-60).

6. Thus, Rosenblum's invention also "relates to a pharmaceutical composition comprising an effective amount of a hydroxy-substituted azetidinone cholesterol absorption inhibitor of formula I, a cholesterol biosynthesis inhibitor, and a pharmaceutically acceptable carrier" (Rosenblum, col. 4, ll. 1-5).

7. Rosenblum discloses:

> Cholesterol biosynthesis inhibitors for use in the combination of the present invention include HMG CoA reductase inhibitors such as lovastatin, pravastatin, fluvastatin, simvastatin, and CI-981; HMG CoA synthetase inhibitors, for example L-659,699 ((E,E)-11-[3'R-(hydroxy-methyl)-4'-oxo-2'R-oxetanyl]-3,5,7R-trimethyl-2,4-undecadienoic acid); squalene synthesis inhibitors, for example squalestatin 1; and squalene epoxidase inhibitors, for example, NB-598 ((E)-N-ethyl-N-(6,6-dimethyl-2-hepten-4-ynyl)-3-[(3,3'-bithiophen-5-yl)methoxy]benzene-methanamine hydrochloride) and other

> cholesterol biosynthesis inhibitors such as DMP-565. Preferred HMG CoA reductase inhibitors are lovastatin, pravastatin and simvastatin.

(Rosenblum, col. 6, ll. 37-39.)

8. Chobanian discloses that the "effects of 9 months of orally administered captopril (25-50 mg/kg body wt/day) on aortic atherosclerosis was examined in normotensive Watanabe heritable hyperlipidemic rabbits. Captopril caused a significant decrease in aortic atherosclerosis" (Chobanian 327 (abstract)).

9. Chobanian discloses that "[t]hese studies indicate that captopril has a potent antiatherosclerotic action in the Watanabe heritable hyperlipidemic rabbit" (Chobanian 327 (abstract)).

10. Chobanian states that "[t]he clinical significance of these findings is unknown" (Chobanian 331). However, Chobanian states, given the "widespread use of captopril and other ACE inhibitors in the treatment of hypertension, further studies need to be performed to determine the mechanism far the antiatherosclerotic effect of captopril in the WHHL rabbit and to examine the influence of the drug on the course of arterial disease in humans" (*id.*).

PRINCIPLES OF LAW

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273 (1976)).

Thus, "when the question is whether a patent claiming the combination of elements of prior art is obvious" the relevant inquiry is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* The Court reasoned that:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421.

As our reviewing court has stated, "[o]bviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

> [T]o have a reasonable expectation of success, one must be motivated to do more than merely to "vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." Similarly, prior art fails to provide the requisite "reasonable expectation" of success where it teaches merely to pursue a "general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."

Medichem S.A. v. Rolabo S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *O'Farrell*, 853 F.2d at 903-04).

As to motivation, while the Supreme Court held that some rationale must be supplied for a conclusion of obviousness, the Court explicitly rejected a "rigid approach" to the obviousness question, and instead emphasized that "[t]hroughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach . . . ." *KSR,* 550 U.S. at 415. The Court also rejected the use of "rigid and mandatory formulas" as being "incompatible with our precedents." *Id.* at 419; *see also id.* at 421 ("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.").

The Court thus reasoned that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

ANALYSIS

Appellants' arguments do not persuade us that the Examiner erred in concluding that claim 1 would have been obvious to an ordinary artisan in view of the teachings of Rosenblum and Chobanian.

It may be true that neither reference explicitly teaches combining its disclosed medicament with therapeutic agents of the type disclosed in the other reference. However, Rosenblum does, in fact, disclose that its compounds of formula I are amenable to combination with any of a number of different cholesterol biosynthesis inhibitors that affect different steps in the cholesterol biosynthesis pathway (*see* FF 5-7). Rosenblum also discloses

that, in addition to the high serum cholesterol treatable by compounds of formula I, hypertension is a risk factor atherosclerotic coronary heart disease (FF 2).

In view of these teachings, we agree with the Examiner that a person of ordinary skill in the art, being a person of ordinary creativity and common sense, *KSR*, 550 U.S. at 418, 421, would have been prompted to combine the high cholesterol-treating compounds of Rosenblum's formula I with Chobanian's widely used hypertension-treating captopril (FF 10), in order to treat two of the risk factors of coronary heart disease. We therefore also agree with the Examiner that a person of ordinary skill in the art would have considered claim 1 prima facie obvious.

We are not persuaded, as Appellants argue (App. Br. 10), that a person of ordinary skill in the art would have been dissuaded from combining the drugs of Rosenblum and Chobanian because the drugs might interact in a deleterious way, or that the drugs might not function together in the same way that they do separately. While Appellants assert that "[t]here is no way of knowing, prior to . . . testing, that the compounds, when administered in combination, will have the same profile as the compounds administered separately," Appellants have provided no evidence to support that assertion.

More importantly, Appellants have not provided any specific evidence suggesting that a person of ordinary skill in the art would have expected the drugs of Rosenblum and Chobanian to interact unacceptably or lack their expected efficacy when combined. It is well settled that argument by counsel cannot take the place of evidence. *In re Cole*, 326 F.2d 769, 773, (CCPA 1964); *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997).

The evidence currently of record is contrary to Appellants' assertions. Specifically, by disclosing that the compounds of formula I can be combined with a variety of different agents that act on different steps in the cholesterol biosynthesis pathway, Rosenblum would have suggested to an ordinary artisan that its compounds were amenable to combination with other agents useful in treating risk factors for atherosclerotic coronary heart disease, such as hypertension. Thus, while a person of ordinary skill may have had some pause when combining certain therapeutic agents, Rosenblum suggests that its drug can be suitably combined with other medicaments.

Moreover, as noted above, "[o]bviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *O'Farrell*, 853 F.2d at 903-04. In the instant case, given the explicit disclosures in Rosenblum and Chobanian that their respective drugs are suitable in treating conditions that are risk factors for atherosclerotic coronary heart disease, a person of ordinary skill would not have had to excessively vary parameters, try numerous possible choices, or explore treatment options with only general guidance, in order to combine the two references' drugs and treat the disease.

We are therefore not persuaded that the claimed combination of ingredients would only have been obvious to try. Moreover, because the Examiner's conclusion of prima facie obviousness is based solely on the disclosures in the prior art, we are not persuaded that the Examiner improperly used hindsight reasoning.

We therefore affirm the Examiner's rejection of claim 1 as obvious over Rosenblum and Chobanian. Claims 3, 22, 23, 33, 34, and 49 fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS -- ROSENBLUM, CHOBANIAN, LELEK, MYASNIKOV, AND SCHAARMANN

ISSUE

Claims 43-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenblum, Chobanian, Lelek, Myasnikov, and Schaarmann (Ans. 5-7).

Claims 43-46 read as follows:

> 43. The composition according to claim 1, further comprising at least one Omega 3 fatty acid.
>
> 44. The composition according to claim 1, further comprising at least one natural water soluble fiber.
>
> 45. The composition according to claim 1, further comprising at least one antioxidant or vitamin.
>
> 46. A pharmaceutical composition for the treatment or prevention of vascular conditions, obesity, diabetes or lowering a concentration of a sterol in plasma of a mammal, comprising a therapeutically effective amount of the composition of claim 1 and a pharmaceutically acceptable carrier.

The Examiner cites Lelek as teaching linolenic acid (an omega-3 fatty acid), Schaarmann as teaching soluble fiber, and Myasnikov as teaching vitamin C, as being "useful for reducing cholesterol and treating arteriosclerosis" (Ans. 5-6). The Examiner concludes that, "[a]s shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-arteriosclerosis agents. It would

follow that the recited claims define prima facie obvious subject matter" (*id.* at 6).

Appellants again contend that a person of ordinary skill in the art would have lacked motivation to combine Rosenblum and Chobanian (App. Br. 14-15). Moreover, Appellants urge, Schaarmann's disclosure is only tenuously relevant to treating atherosclerosis, and Lelek and Myasnikov do not suggest combining their disclosed compounds with other therapeutic agents, "nor the combination of compounds specifically claimed in Claim 1" (*id.* at 16).

Appellants contend that following "the reasoning presented in the Office Action, one skilled in the art would combine every compound that may have some minor activity in treating some aspect of hyp[er]cholesterolemia, which can encompass thousands of compounds. Yet no guidance is provided as to the selection of particular combinations of classes of compound" (*id.*).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner erred in concluding that claims 43-46 would have been obvious to an ordinary artisan where, as discussed above, Rosenblum and Chobanian would have rendered compositions including compounds of formula (I) and captopril prima facie obvious due to their capacity to treat risk factors for atherosclerotic coronary art disease, and where Lelek, Schaarmann, Myasnikov, respectively, further teach omega-3 fatty acids, soluble fiber, and vitamin C, as being useful for reducing cholesterol and treating arteriosclerosis.

FINDINGS OF FACT

11. Lelek discloses a study in which Leghorn roosters rendered atherosclerotic by administration of cholesterol were co-administered Linacidin, a product containing equal amounts of linoleic and linolenic acids (Lelek, abstract).

12. Lelek states that atherosclerosis was prevented when Linacidin was administered together with the cholesterol. Pyridoxine increased Linacidin's therapeutic effect (Lelek, abstract).

13. Schaarmann discloses that a "human experiment with 9 women was carried out to measure the interrelationship between the intake of soluble dietary fibre and the faecal excretion of tocopherol. The volunteers consumed additionally 40 g oats bran per day after a control period without bran supplement" (Schaarmann 689).

14. Schaarmann discloses that "the apparent absorption of tocopherol increased by 6 %. The concentration of the total cholesterol did not change, however, the ratio of HDL- to LDL-cholesterol was positively influenced" (Schaarmann 689). Specifically, "the ratio of LDL-/HDL-cholesterol was significantly improved by about 1.0 units (from 3.3 to 2.3 $p<0.05$)" (*id.* at 694).

15. Myasnikov discloses a study on the influence of vitamins on elevated cholesterol and experimentally induced atherosclerosis (Myasnikov, abstract).

16. Myasnikov found that continued use of vitamin C by patients with hypertension and atherosclerosis lowered their elevated cholesterol levels, and that vitamin C reduced blood cholesterol in rabbits having experimentally induced atherosclerosis (Myasnikov, abstract).

ANALYSIS

Appellants' arguments do not persuade us that the Examiner erred in concluding that claims 43-46 would have been obvious to an ordinary artisan in view of the cited references' teachings. While it is true that Schaarmann's study focuses on the effect of soluble fiber on tocopherol absorption, Schaarmann also discloses that fiber had a significant positive effect on the patients' HDL/LDL balance (FF 14). Similarly, both Lelek and Myasnikov disclose that linolenic acid and vitamin C have positive effects on atherosclerosis and elevated cholesterol, respectively (FF 12, 16).

Given these teachings that the disclosed agents exerted positive effects on factors involved in atherosclerotic coronary heart disease, we agree with the Examiner that a person of ordinary skill in the art would have been prompted to include each of the agents in a composition containing Rosenblum's compound and Chobanian's captopril. We therefore also agree with the Examiner that a person of ordinary skill in the art would have considered claims 43-45 obvious in view of the cited references. Moreover, in view of Rosenblum's disclosure of the suitability of pharmaceutical carriers in such compositions (FF 6), we also agree with the Examiner that claim 46 would have been prima facie obvious.

We do not agree with Appellants that the issue is whether a person of ordinary skill in the art to would have combined every possible anti-atherosclerotic active agent into a single composition. Rather, the issue is whether a person of ordinary skill in the art would have considered it obvious to combine any one of the three ingredients recited in claims 43-45 into an anti-atherosclerotic composition that also contained a compound disclosed by Rosenblum and captopril.

As discussed above, because each of the ingredients is disclosed in the art as having a beneficial effect on a factor affecting atherosclerotic coronary heart disease, we agree with the Examiner that a person of ordinary skill in the art would have been prompted to combine any one of the three agents recited in claims 43-45 into a composition that also contained a compound disclosed by Rosenblum and captopril so as to treat or prevent the disorder. Appellants do not point to any evidence suggesting that the agents function in an unexpected manner. We therefore affirm the Examiner's rejection of claims 43-45, as well as claim 46.

SUMMARY

We affirm the Examiner's rejection of claims 1, 3, 22, 23, 33, 34, and 49 under 35 U.S.C. § 103(a) as being unpatentable over Rosenblum and Chobanian.

We also affirm the Examiner's rejection of claims 43-46 under 35 U.S.C. § 103(a) as being unpatentable over Rosenblum, Chobanian, Lelek, Myasnikov, and Schaarmann.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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